DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

February 25, 2000

WARNING LETTER

Ms. Gloria J. Thesenvitz, President
Nova-Tech, Inc.
1982 E. Citation Way
Grand Island, NE 68801

Ref #: KAN 2000-009

Dear Ms. Thesenvitz:

During an inspection of your veterinary drug manufacturing and medical device facility conducted on December 7-9, 1999, our investigator found significant deviation from the Good Manufacturing Practice for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 [21 CFR 211]. Such deviations cause veterinary drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found:

- No specific Standard Operating Procedures (SOPs) for aseptic filling operation [21 CFR 211.100(a)].

- Inadequate controls of microbiological contamination [21 CFR 211.113(b)].

- Inadequate equipment cleaning documentation and procedures [21 CFR 211.182].

- Physical plant defects and the need for repairs of some areas [21 CFR 211.42].

The above listed items are not intended to be an all-inclusive list of Good Manufacturing Practice violations. As a manufacturer of veterinary pharmaceuticals it is your responsibility to assure your operations and the products you manufacture and distribute are in compliance with the law.

We acknowledge your response to the FDA 483 dated December 29, 1999 and the corrections you had completed by that date. We request that you provide us with documentation of the corrections promised according to the time line provided in your letter response.

You are requested to forward your response to this letter within fifteen (15) working days detailing those still pending corrective actions. Your reply should be directed to Ralph J. Gray, Compliance Officer at the above address.

Sincerely,

Mary Walleske for

Donald L. Walker
Acting District Director
Kansas City District Office

RJG:tlw